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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,473	05/31/2000	BARBARA BOTTAZZI	BJS-2801-18	9420

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
05/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/555,473	BOTTAZZI ET AL.	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-29* is/are pending in the application.

4a) Of the above claim(s) *20-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 November 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence Alignment*.

RESPONSE TO APPLICANT'S AMENDMENT

1. Claims 17-29 are pending.

2. Newly added claims 20-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

3. Applicant's amendment filed 02/05/2007 is acknowledged.

4. Claims 17-19 are currently under examination as they read on a PTX3 pharmaceutical composition.

5. The corrected drawings filed on 11/20/2002 are acknowledged.

6. In view of the amendment filed on 02/05/2007, only the following rejections are maintained.

7. Applicant argues that the present examiner should give full faith and credit to the prior Examiner's Office Actions and has cited MPEP § 706.04.

It is noted that MPEP § 706.04 applies to 'Rejection of Previously Allowed Claims.' There have been no allowed claims in the prosecution history of this case, so this section of the

MPEP does not apply. In addition, the previous action was signed by Maher Haddad, who is a Primary Examiner.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 17-19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Alles et al. (PTO-892, filed on 12/20/2001) for the same reasons as set for the in the Office Action mailed on 10/26/2006.

Alles et al. teaches 1.) a composition comprising naturally occurring human PTX3 from human peripheral blood mononuclear cells and a pharmacologically acceptable excipient (i.e. saline) injected subcutaneously into an animal (In particular, pages 3483-3485 and 3489, whole document); and 2.) mature human PTX3 protein isolated from the supernatant of COS cells incubated in DMEM for Western analyses (In particular, page 3485, whole document). Claim 17 is anticipated by the pharmaceutical PTX3 protein composition in COS cell supernatant containing DMEM.

A composition is a composition, regardless of its intended use. Therefore, the reference teachings anticipate the claimed invention.

Applicant arguments filed on 02/05/2007 have been fully considered, but are not been found convincing.

Applicant argues that DMEM is not a pharmaceutically acceptable excipient and that the present examiner has not provided any evidence to support that DMEM is a pharmaceutically acceptable excipient. Applicant points to the components of DMEM, nicotinamide, folic acid, choline chloride and myo-inositol in particular, to support that DMEM is not a pharmaceutically acceptable excipient because these components have their own therapeutic effects. Applicants also assert that the PTX3 protein composition described in Alles et al. is dissolved in a solution that "more likely than not, may be toxic and/or infective" and is therefore not administerable as a pharmaceutical composition.

However, it is the examiner's position that since the specification does not provide any limiting definition of pharmaceutical carriers, the prior art's DMEM would appear to be encompassed by the broadest reasonable definition of a "pharmaceutically acceptable excipient." Giving the term its broadest reasonable definition, DMEM is not incompatible with pharmaceutical use; therefore it is encompassed by the term. Further, as applicant has requested,

the examiner has supplied two evidentiary references employing DMEM in a pharmaceutical use. Berry et al. (PTO-892, Reference U) injects mesenchymal stem cells diluted in DMEM into rats as a therapy (In particular, page H2196 right column, last paragraph, whole document). Dai et al. (PTO-892, Reference V) injects Hec50co cells into athymic mice in DMEM medium (In particular, page 170 second to last paragraph in left column, whole document).

PTX3 in DMEM solution, which may contain "metabolites, catabolite and residual components of the cellular lysis, such as virus related or released by the DNA of the COS cells", is still a pharmaceutical composition. The term "containing" in Claim 17 is open language allowing for the pharmaceutical composition to contain substances other than PTX3 and a pharmaceutically acceptable excipient, such as the aforesaid metabolites. FDA regulations regarding pharmaceutical preparations and the guidelines thereto are not persuasive in the instant case, as the claims are not limited to human use. However, even if the claims were limited to human use, the reference teachings anticipate the claimed invention because the specification provides no guidance as to the level of purity of the pharmaceutical composition. Therefore, PTX3 in DMEM solution containing potential impurities is "not incompatible with pharmaceutical use."

Further, it is noted, as evidenced by the specification on page 9, lines 15-19, that the term "pharmaceutical composition" is enabled by the injection of cells of P815 PTX3-producing clones (including cell metabolites, catabolites and residual components of cellular lysis) into

mice. Therefore, if the specification is enabled for PTX3 pharmaceutical use by the injection of PTX3-producing cells into mice, then the prior art is enabled for the same pharmaceutical use.

The reference teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 17-19 stand rejected under 35 U.S.C. 103(a) as being anticipated by Gewurz et al. (PTO-892 filed on 10/05/2006), in view of U.S. Patent No. 5,426,181 (PTO-892, filed on 05/28/2004) as evidenced by Brevario et al (PTO-892 mailed 09/23/2004; Reference U) for the same reasons as set forth in the Office Action mailed on 10/05/2006.

Applicant arguments filed on 02/05/2007 have been fully considered, but are not been found convincing.

Applicant argues that the '181 reference fails to teach the 381 amino acid sequence of PTX3 of the present application because TSG-14 is different by one amino acid from PTX3 and that there is not suggestion to alter the sequence of the patented protein at position 202 from a leucine to a methionine.

However, it is the examiner's position that the 5,426,181 reference teaches TSG-14, known in the prior art as the same molecule as PTX3 (see Gewurz et al., in particular page 56), having a human sequence of 381 amino acids with an 17 amino acid signal sequence that is 100% identical to SEQ ID NO. 1 of the instant application (In particular, page 56, last paragraph referring to Brevario et al reference 25; and attached sequence alignment from Bravario et al.). The reference teaches the full-length and mature TSG-14 proteins in a pharmaceutical composition with a pharmaceutically acceptable excipient for the treatment of tumors or infections (In particular, column 6, lines 56-57 and columns 32-34).

One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention because 1.) PTX3 is homologous to CRP, which is another pentraxin family member shown to activate complement, bind leukocytes and elicit anti-tumor activity; 2.) the prior art taught the full-length protein of SEQ ID NO:1 and the mature protein of amino acids 18-381 of SEQ ID NO:1 and 3.) the prior art taught the full-length protein of SEQ ID NO:1 and the mature protein of amino acids 18-381 of SEQ ID NO:1 with the exception of one amino acid difference at position 202 (TSG-14) in pharmaceutical composition for treatment of tumors or infections.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expection of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. No claim is allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937.

The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 17, 2007
Nora M. Rooney, M.S., J.D.
Patent Examiner
Technology Center 1600

MAHER M. HADDAD
PRIMARY EXAMINER